

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32, 33, 144 and 145 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. It appears that the specification does not provide support for the following limitations:

The limitations of copolymer at 25%, 35%, 45% and 55% recited in claims 32 and 144 are not recited in examples 1-53 as pointed out by the Applicant in the Remarks filed 08/08/11.

The limitations of copolymer at 63% and 62.75% recited in claims 33-145 are not recited in examples 1-53 as pointed out by the Applicant in the Remarks filed 08/08/11.

In accordance with MPEP § 714.02, applicant should specifically point out support for any amendment made to the disclosure.

Claims 1-14,16-33,35,38-40,71-88,90-97,112-132 and 134-147are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the

specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: 1) breadth of the claims, 2) nature of the invention, 3) state of the prior art, 4) amount of direction provided by the inventor, 5) the level of predictability in the art, 6) the existence of working examples, 7) quantity of experimentation needed to make or use the invention based on the content of the disclosure, and 8) relative skill in the art. All of the factors have been considered with regard to the claim, with the most relevant factors being discussed below:

***Breadth of the claims:*** independent claims 1 and 73 are directed to a composition comprising a copolymer of methyl acrylate, methyl methacrylate and methacrylic acid, wherein the composition is substantially pH-independent.

***State of the prior art:*** the prior art teaches that copolymer of methyl acrylate, methyl methacrylate and methacrylic acid is known to have pH-dependent property. See for example teachings in Chiao et al. (paragraph 0049), Heinicke (paragraph 0033), and He et al. (paragraph 0011). The present specification does not provide any adequate guidance for the limitation "substantially pH-independent". According to the teachings in the prior arts, it is not understood how the claimed copolymer, which is known in the art as a pH-dependent polymer, is indeed, a pH-independent in the present case.

As such, the practitioner would turn to trial and error experimentation in order to compose a composition comprising a copolymer of methyl acrylate, methyl methacrylate

and methacrylic acid, wherein the composition is substantially pH-independent, without guidance from the specification.

***The quantity of experimentation:*** there is a substantial gap between a composition comprising the claimed copolymer, and one comprising the same copolymer but obtain different properties. As stated earlier, the prior arts teach that copolymer of methyl acrylate, methyl methacrylate and methacrylic acid is pH-dependent. Consequently, a burdensome amount of research would be required by one of ordinary skill in the art to bridge this gap.

***The relative skill of those in the art:*** the skill of those in the art is very high, e.g., Ph.D. or M.D. level technology.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 73-88, 90-97, 112-132 and 134-147 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 73 recites the phrase "wherein...the outer surface upon being exposed to a gastro-intestinal environment dissolves in a time/controlled release dependent manner" in the last three lines. It is not quite clear whether the capsule shell will dissolve or only the outer surface will dissolve? It is also not entirely clear how the active agent inside the capsule releases when there is only the outer surface of the capsule will be dissolved.

***Response to Arguments***

Applicant's arguments filed 08/08/11 have been fully considered but they are not persuasive.

Applicants argue that one of skill in the art would clearly understand the patent application as providing clear direction how to make the claimed invention. For example, the specification provides a detailed disclosure and teaching about pH-independence of the copolymers:

One aspect of the present invention is the novel blending of components which has the ability to render the poly(meth)acrylates, such as 4135F, which are pH dependent independent of this characteristic. They are no longer governed by the pH of the solution, i.e. the gastric tract, but are time/controlled release dependent instead, which determination is based upon the addition of the swellable solids and surfactants. (Specification: pg. 24, lines 33-36; pg.25, lines 1-2).

However, as admitted by the Applicant, the polymer itself is a pH dependent, which will render independent only by the addition of the swellable solids and surfactant (emphasize added). The Examiner notes that the required swellable solids and surfactants however, are not recited in the present independent claims.

Applicants further argue that the Examples describe in detail how to manufacture a variety of multicomponent pharmaceutical dosage forms with the correct blending of components that will render the copolymers to be pH independent. (Specification: pg. 37-49). Example 1 illustrates the "process used to mold the various multicomponent capsules and appropriate subunits." (Specification: pg. 37-38). Examples 1-53 show that these copolymers are time/controlled release dependent. (Specification: pg. 37-49). The guidance provided in the description in the specification, and in the examples is

sufficient to enable one of skill in the art to practice the invention over the full scope of the claims.

However, as discussed above, many of the required components detrimental to render the pH-dependent polymer pH-dependent property are perhaps not recited in the rejected claims. It is noted that the present claimed polymer, namely, Eudragit P-4135F is known in the art as a pH-dependent polymer. See for example the teaching of Lamprecht et al.'s abstract.

Accordingly, the 112, first paragraph rejections are maintained for at least the above reasons.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/  
Primary Examiner, Art Unit 1615